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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,259	11/14/2003	Elaine Merisko-Liversidge	029318-0979	8061

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EXAMINER	
VANIK, DAVID L	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,259	MERISKO-LIVERSIDGE, ELAINE	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) *16,19-23 and 40-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17,18 and 24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/18/04; 2/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's response to the Election/Restriction requirement filed on 2/9/2006.

Election/Restrictions

Applicant's election with traverse of Claims 1-15 and 17-39 in the reply filed on 2/9/2006 is acknowledged. The traversal is on the ground(s) that the search and examination of all of the groups does not present the examiner with a search burden. This is not found persuasive because Groups I-IV differ in scope as judged by their different classification. Additionally, because Groups I and II comprise patentably distinct inventions, an additional search would be required in order to examine the patentability of Groups I and II together. The examiner also notes that Applicant has elected "less than about 1900 nm," "crystalline particles," "cardiovascular agents," and "non-ionic surface stabilizer" in response to the species election requirement. As a result of the species/restriction elections, claims 16, 19-23, 40-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/9/2006. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 17, 24-39 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,540,602 ('602).

'602 disclose pharmaceutical compositions and processes for producing said pharmaceutical compositions (abstract). The pharmaceutical compositions can comprise drugs that are scarcely water soluble, such as nifedipine (abstract and Example 8). As set forth in Example 8, nifedipine was combined with squalane, gum arabic, and gelatin to form a particle-based pharmaceutical composition with good redispersability in water (See Example 8). Gum arabic and gelatin are suitable surface modifiers and squalane is a suitable non-nifedipine active agent. According to '602, the nifedipine-based particles have a diameter between 0.1 – 3.0 microns (Example 8).

It is the examiner's position that, inherently, the composition advanced by '602 has T_{max},C_{max}, bioequivalence, absorption, and AUC properties consistent with those enumerated in the instant claims set. Since the essential elements of the '602 composition are identical to the instant compositions (that is, a nifedipine particle of less than 2 microns together with a surface stabilizer), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant

application. As such, it is the examiner's position that the composition advanced by '602 anticipates the compositions enumerated in the instant claim set.

Claims 1-15, 17, 24-39 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2166651 ('651).

'651 disclose controlled release particle compositions comprising microparticles with an average size in the range of 0.1 to 125 microns (abstract). Said particle-based composition can further comprise excipients and at least one-nontoxic polymer (page 1, lines 19-61). Polymer compositions suitable for use in the '651 composition include alkyl and hydroxyalkyl celluloses, polyvinylpyrrolidone, and polymers of acrylic and methacrylic esters (page 1, lines 39-61). As confirmed in the instant specification, these polymers are suitable surface modifiers (See pages 28-34 of the instant specification). As confirmed in Example 3, nifedipine is a suitable pharmaceutical agent (also see page 2, lines 48-54).

It is the examiner's position that, inherently, the composition advanced by '651 has T_{max},C_{max}, bioequivalence, absorption, and AUC properties consistent with those enumerated in the instant claims set. Since the essential elements of the '651 composition are identical to the instant compositions (that is, a nifedipine particle of less than 2 microns together with a surface stabilizer), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant

application. As such, it is the examiner's position that the composition advanced by '651 anticipates the compositions enumerated in the instant claim set.

Claims 1-15, 17, 24-39 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,562,069 ('069).

'069 disclose compositions comprising nifedipine useful for treating cardiovascular and coronary disorders (abstract). According to '069, nifedipine crystals having a mean particle diameter of about 1 to 10 microns can be combined with a suitable surface stabilizer, such as PVP or methylcellulose, to form the composition (column 2, lines 23-31 and Examples 1-7).

It is the examiner's position that, inherently, the composition advanced by '069 has T_{max},C_{max}, bioequivalence, absorption, and AUC properties consistent with those enumerated in the instant claims set. Since the essential elements of the '069 composition are identical to the instant compositions (that is, a nifedipine particle of less than 2 microns together with a surface stabilizer), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '069 anticipates the compositions enumerated in the instant claim set.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15, 17-18, and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,814,175 ('175) in view of Us 5,145,684 ('684).

'175 teach combination preparations comprising particulate nifedipine together with a Beta Blocker (abstract). Said combination preparations are useful for treating cardiovascular diseases (abstract). According to '175, a number of distinct surface modifiers, such as PVPP, cellulose, and sodium alginate, may be added to the nifedipine-based compositions (column 4, line 39 – column 2, line 11).

'175 is deficient in the sense that it teaches nifedipine-particulate compositions with a particle diameter of between 10 – 50 microns (column 1, lines 39-57). However,

'684 provides motivation for formulating the particles of a poorly soluble drug (such as nifedipine) into a form that is less than 400 nm (column 2, lines 31-66). According to '684, when poorly soluble drugs are combined with a surface stabilizer and formulated into a form having an effective average particle size of less than 400 nm, said composition exhibits remarkably high bioavailability (column 2, lines 31-62). Because a composition comprising a poorly soluble drug and a surface modifier in an amount sufficient to maintain an effective particle size of less than 400 nm exhibits remarkable bioavailability, one of ordinary skill in the art would have been motivated formulate the nifedipine - based composition advanced by '175 into a particulate having an effective average particle size of less than 400 nm. Based on the teachings of '684, there is a reasonable expectation that a composition comprising nifedipine (a poorly soluble drug) together with a surface modifier in an amount sufficient to maintain an effective particle size of less than 400 would result in a composition having remarkable bioavailability. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the nifedipine - based composition advanced by '175 into a particulate form having an effective average particle size of less than 400 nm in view of the teachings of '684.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

4/21/06

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